UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: INSULIN PRICING LITIGATION	**Case 2:23-md-03080** **MDL No. 3080** **JUDGE BRIAN R. MARTINOTTI** **JUDGE RUKHSANAH L. SINGH**

THIS DOCUMENT RELATES TO: ALL ACTIONS

JOINT PROPOSED DISCOVERY PLAN[1]

1. Set forth the name of each attorney appearing, the firm name, address and telephone number and facsimile number of each, designating the party represented.

See Attachment A.

2. Set forth a brief description of the case, including the causes of action and defenses asserted.

Plaintiffs' Summary

Diabetes is an epidemic throughout the country; nearly 40 million people in the United States have diabetes and another 100 million people have prediabetes. The financial burden caused by diabetes is equally staggering with healthcare and payor costs attributable to diabetes treatment soaring to over $300 billion in 2022 alone.

The majority of diabetics rely on insulin and GLP-1s/Type 2 treatments to survive. Pharmaceutical manufacturers Eli Lilly, Novo Nordisk, and Sanofi ("Manufacturer Defendants") manufacture 99% of the insulins currently on the market. Since 2003, the Manufacturer Defendants have raised the list prices of their diabetic drugs in an astounding manner. The diabetic treatments at issue in this litigation that cost less than $5 to produce and that were originally priced at $20 when released, now range between $300 and $700. Plaintiffs allege that the spike in pricing results from a concerted effort between the Manufacturer Defendants and the largest pharmacy benefit managers, Express Scripts, CVS Caremark, and OptumRx ("PBMs" or "PBM Defendants").

[1] This Joint Discovery Plan is submitted on behalf of all tracks (State Attorney General Track, Self-Funded Payer Track, and Third-Party Payer Class Track in the MDL and the coordinated action *In re Direct Purchaser Pricing Litigation*, No. 20-cv-3426 (the "Direct Purchaser Action") (collectively, the "subject actions").

The PBM Defendants (Express Scripts, Optum, and CVS Caremark) control over 80% of the pharmaceutical market, managing pharmacy benefits for over 270 million Americans. As part of this work, these PBMs establish standard formularies (tiered drug lists) that, among other things, set the baseline for which diabetes medications are paid for (and which are not) and with what restrictions for nearly every diabetic and payor in the United States. Through these tiered drug formularies, the three companies control which drugs are available to almost every diabetic in the United States. If a drug is excluded from these PBMs' formularies, it will not be available for the majority of diabetics throughout the United States.

The Manufacturer Defendants likewise understand that these PBMs' standard formularies influence diabetic drug accessiblity throughout the country. The unfair and deceptive conduct driving the precipitous price increases for these drugs—the Insulin Pricing Scheme—was born from this mutual understanding. Both the Manufacturer Defendants and the PBMs play vital roles and profit immensely from the Insulin Pricing Scheme.

The Insulin Pricing Scheme works as follows: first, to gain formulary access from the PBMs for their diabetic treatments, the Manufacturer Defendants publish only artificially inflated and misleading prices for their whole suite of diabetic treatments (insulins and GLP-1s/Type 2 treatments), which then serve as the basis for significant, yet undisclosed, payments back to the PBMs. These payments are provided under a variety of labels—rebates, discounts, credits, inflation/price protection fees, administration fees, etc. Yet, however they are described, these payments along with the inflated reported prices, are *quid pro quo* for inclusion on the PBMs' standard formularies. PBMs grant preferred formulary status based upon the highest inflated price and upon which diabetes medications generate the largest profits for these PBMs. The the higher the false price, the more money the PBMs receive. Further, the PBM Defendants exclude (or disadvantage) lower priced insulins and other diabetic treatments from their formularies because these drugs are less profitable for the PBMs. By doing so, the PBMs restrict diabetics' and payors' access to these lower priced diabetic treatments. In addition, the PBM Defendants also use these false prices throughout their customer contracts; they insist that all payments made by their client plans be based on same; they ensure the proliferation of the false prices throughout their vast pharmacy, provider and covered life networks.

The Insulin Pricing Scheme creates a "best of both worlds" scenario for the Manufacturer Defendants and the PBMs. The Manufacturer Defendants are able to make these payments to buy preferred formulary position—which significantly increases their revenue—without sacrificing their profit margins. The PBMs profit off the Insulin Pricing Scheme in numerous ways, including: (1) retaining a significant—yet undisclosed—percentage of these manufacturer payments, (2) using the price produced by the Insulin Pricing Scheme to generate profits from pharmacies in the PBMs' networks and (3) relying on those same artificial prices to drive up the PBMs' margins for their own retail and mail order pharmacies.

This conduct is deceptive and unfair from the perspective of both the Manufacturers and the PBMs; in other words each Defendant is both independently and jointly/severally liable for their conduct.

Because the price of nearly every diabetes medication in the country is based upon the limited and false pricing generated by the scheme at issue in this case, every diabetic and payor in the United States who purchases these life-sustaining drugs has been directly and detrimentally impacted. While the Insulin Pricing Scheme has resulted in record profits for PBMs and the Manufacturers, it has made insulin and GLP-1s unaffordable for many diabetics and created an immense financial burden for payors across the country and the overall healthcare system. It is for this reason that no fewer than 10 State Attorneys General have now filed suit and banded together in this MDL. It is for this reason the FTC is investigating the PBMs and their affiliated rebate aggregators. It is for this reason the federal government is scrutinizing the Manufacturers and the PBMs. The PBMs and Manufacturers' coordinated misconduct has directly harmed every diabetic and payor in the country. This case seeks to bring justice for those individuals and to bring an end to this Defendants' scheme once and for all.

Defendants' Summary

Plaintiffs in these cases allege that well-known features of the American healthcare system are part of a supposedly illegal "scheme" between Pharmacy Benefit Managers and Manufacturers. Their central allegation claims the fact that insulin manufacturers pay rebates to PBMs in order to secure placement for their insulin products on PBM formulary offerings (just as other manufacturers do for countless other drugs) is a "scheme" to raise the price of insulin. And they label the rebates "secret payments," even though the fact that PBMs negotiate rebates with manufacturers has been common knowledge for decades, and both manufacturers and PBMs have made extensive public disclosures about rebates.

According to Plaintiffs, this system has "artificially inflated" the price of insulin and has caused the Manufacturers to publish "deceptive" list prices. But, as the Tenth Circuit recognized in rejecting materially identical claims, the practices Plaintiffs challenge are "normal competitive tool[s]." *In re EpiPen Marketing, Sales Practices and Antitrust Litigation*, 44 F.4th 959 (10th Cir. 2022). And this Court recently noted that it "does not see" how the Manufacturers could report their prices in some other manner "without causing Defendants to violate federal law." *In re Insulin Pricing Litig.*, 2024 WL 416500, at *28 (D.N.J. 2024).

The Manufacturer Defendants are pharmaceutical companies that research, develop, manufacture, and sell prescription drugs, including insulin and other diabetes medications. Manufacturers sell drugs to nonparty wholesalers at a published "list price" aptly called the Wholesale Acquisition Cost, or "WAC." WAC is "the manufacturer's list price for the drug or biological … not including prompt pay or other discounts, rebates, or reductions in price." 42 U.S.C. § 1395w-3a(c)(6)(B). After wholesalers purchase medications at WAC, they sell the products to pharmacies, which in turn sell them to patients.

The PBM Defendants contract with health plans and other third party-payors to administer prescription drug benefits. In that role, PBMs develop preferred drug lists or formularies that their payor clients may adopt or customize when designing their own prescription benefits and coverage for their members, including copays and other cost sharing. PBMs also negotiate to obtain rebates from drug manufacturers, which can lower PBMs' clients' net drug costs.

Rebates are an embedded—and, in some cases, mandated—feature of the U.S. healthcare system. For decades, pharmaceutical manufacturers and PBMs have entered rebate agreements for hundreds of medicines, and PBMs have developed formulary offerings for their clients based on, among other considerations, the net cost after such rebates when clinically appropriate.

PBMs are not alone in negotiating rebates from manufacturers and developing formularies based on those rebates. Since 1991, the Centers for Medicare & Medicaid Services ("CMS") has required manufacturers to enter into "rebate agreement[s]" with federal and state entities for Medicaid. 42 U.S.C. § 1396r-8(a)(1). In addition, most states, including many Plaintiff states in the MDL, leverage preferred drug lists to negotiate supplemental rebates from drug manufacturers. These fundamental aspects of the healthcare system are not unique to insulin, have never been a secret, and are not unlawful.

Plaintiffs' claim that "nearly every diabetes medication in the country is based upon the prices generated by the Insulin Pricing Scheme" is incoherent–and in fact, is not actually pled in any complaint in the MDL. Plaintiffs have made plain that they would like to expand the scope of this MDL to apply to virtually any medication that any individual with diabetes may take, including non-insulin drugs. This confirms that Plaintiffs' legal theory has no limiting principle: Because pharmaceutical manufacturers pay rebates in connection with essentially *all* of the drugs they sell, Plaintiffs can characterize all drug pricing as resulting from a "scheme." Plaintiffs' attempt to expand the scope of this MDL through sweeping discovery of non-insulin products, if permitted, will only complicate, and delay, the resolution of these matters.

3. Have settlement discussions taken place?

No.

4. Have the parties met pursuant to Fed. R. Civ. P. 26(f)?

The parties met pursuant to Federal Rule of Civil Procedure 26(f) on December 21, 2023, via teleconference. The parties continued discussions regarding a discovery plan on March 27, 2024, and April 5, 2024, and exchanged draft discovery plans.

Plaintiffs' Position: The parties will schedule additional times to conclude that conference, as well as the E-Discovery conference required under Local Civil Rule 26.1(d), in the near future.

Defendants' Position: The parties have already conducted the required FRCP 26(f) conference, consistent with Local Civil Rule 26.1, culminating in (1) submitting competing ESI Protocols governing items identified in Local Civil Rule 26.1(d)(3), and attendant position papers for the Court; and (2) the exchange of competing discovery plan CMOs and submission of each party's respective position paper to the Court.

5. Have the parties exchanged the information required by Fed. R. Civ. P. 26(a)(1)?

No. The parties agree that within 30 days of entry of an Order adopting a Discovery Plan, each Plaintiff and each Defendant, to the extent they have not already done so,[2] will provide one set of initial disclosures pursuant to Federal Rule of Civil Procedure 26(a)(1)(A), to apply across the member actions.

6. Explain any problems in connection with completing the disclosures required by Fed. R. Civ. P. 26(a)(1).

None to report.

7. Have the parties filed disclosures of third-party litigation funding?

No. The parties agree that within 14 days after entry of an Order adopting a Discovery Plan, all parties shall file the disclosures of third-party litigation funding required under Local Civil Rule 7.1.1.

8. Have the parties conducted discovery other than the above disclosures?

Yes. A summary of the discovery conducted in each member case, and coordinated cases, is presented below:

State Attorney General Track

Discovery had commenced in the following State Attorney General cases:

- *State of Mississippi, ex rel. Lynn Fitch, Attorney General v. Eli Lilly and Company, et al*, Case No. 2:23-cv-04364;
- *State of Kansas, ex rel. Kris Kobach, Attorney General v. Eli Lilly and Company, et al*, Case No. 2:23-cv-04219;
- *State of Illinois, ex rel. Kwame Raoul, Attorney General v. Eli Lilly and Company, et al*, Case No. 2:2-cv-04242;
- *State of Montana, ex rel. Austin Knudsen, Attorney General v. Eli Lilly and Company, et al.*, Case No. CV-22-97; and
- *State of Arkansas, ex rel. Tim Griffin, Attorney General v. Eli Lilly and Company, et al*, Case No. 2:23-cv-04239.

[2] As discussed in No. 8 below, the parties in the Direct Purchaser Action and in four of the State Attorney General actions exchanged Rule 26(a)(1) initial disclosures prior to the formation of this MDL.

Prior to transfer, the parties met pursuant to Rule 26(f) in each of these five cases. In all but the Montana case, the parties exchanged initial disclosures. The parties in the Arkansas, Kansas, and Mississippi AG Cases agreed to a stipulated protective order and ESI protocol, served written discovery, and document productions were underway. Manufacturer Defendants had re-produced documents from the consumer class case to the Mississippi and Kansas AGs. Discovery was stayed in each of the cases when this MDL was formed.

Self-Funded Payer Track

No discovery has taken place in the Self-Funded Payer Track.[3]

Third-Party Payer Class Track

No discovery has taken place in the Third-Party Payer Class Track.

Direct Purchaser Action

The parties in the Direct Purchaser Action have exchanged initial disclosures pursuant to Federal Rule of Civil Procedue 26(a)(1) and served (and responded to) interrogatories and requests for production. Based on the allegations in the Direct Purchasers' complaint, the Court determined the discovery time period to be 2012–2018, while also recognizing that there may be specific requests falling outside of that time period and preserving Direct Purchasers' right to seek such discovery upon a showing that the need for such materials outweighed any burden. Some document productions also occurred, including the Manufacturer Defendants' reproduction of nearly a million documents and data from the consumer class case. No depositions have taken place yet in the Direct Purchaser Action.

Consumer Class Action

Significant discovery from the Manufacturer Defendants has been conducted in *In re Insulin Pricing Litig.*, No. 2:17-cv-00699 (D.N.J) which is prospectively being coordinated with the MDL, and fact discovery has closed in that case. Manufacturer Defendants have produced nearly a million documents in response to consumer class plaintiffs' RFPs, have litigated several disputed discovery issues, and have reproduced many of those documents to certain plaintiffs.

9. Proposed joint discovery plan:

The parties intend to conduct comprehensive discovery concerning the subject matter of the claims and defenses. The parties have attached competing Case Management Orders setting forth each side's proposed discovery plan. Plaintiffs' proposed discovery plan is attached as

[3] In *Jackson County, Missouri v. Eli Lilly and Company, et al.* (Case No. 2:23-cv-04531), the parties had submitted a Joint Rule 26(f) Report and Proposed Schedule prior to transfer to this MDL. In addition, Jackson County had served written discovery requests, and Defendants had served their objections.

Exhibit 1. Defendants' proposed discovery plan is attached as Exhibit 2. A redline comparing the two CMOs is attached as Exhibit 3.

10. Do you anticipate any special discovery needs (i.e., videotape/telephone depositions, problems with out-of-state witnesses or documents, etc.)? If so, please explain.

The parties will negotiate a separate protocol governing depositions. To the extent that witnesses and documents are located outside of the United States, which may cause delays in obtaining such discovery, the parties will meet and confer on these issues as they arise and advise the Court. Defendants do not agree that witnesses or documents located outside of the United States are relevant to this MDL. Plaintiffs disagree as made evident, *inter alia,* by their allegations concerning alleged foreign-based PBM rebate aggregator activities and individuals involved therewith. *See, e.g., State of Utah, ex. rel. Sean Reyes, Attorney General v. Eli Lilly & Co., et al.*, Case No. 2:24-cv-0536 (D.N.J.), Dkt. 1-1 (Complaint, filed Nov. 16, 2023) at ¶¶ 392-402.

11. Do you anticipate any issues about disclosure or discovery of electronically stored information, including the form or forms in which it should produced?

The parties have been negotiating a proposed ESI Order since November 2023. Pursuant to the Court's direction during the March 12, 2024 case management conference, the parties filed submissions in support of their proposed ESI Orders (ECF Nos. 120, 123), appeared for a case management conference on April 8, 2024, to discuss their submissions, and submitted supplemental declarations on May 1, 2024.

12. Do you anticipate entry of a Discovery Confidentiality Order?

The Court entered the parties' Stipulated Confidentiality Order on March 21, 2024 (ECF No. 117).

13. Do you anticipate any discovery problems not listed above? Describe.

Other than those identified herein or in the parties' competing discovery proposals, none at this time. If additional issues arise, the parties will follow the Court's preferences and the Local Civil Rules.

14. State whether this case is appropriate for voluntary arbitration (pursuant to Local Civil Rule 201.1 or otherwise) or mediation (pursuant to Local Civil Rule 301.1 or otherwise). If not, explain why and state whether any such procedure may be appropriate at a later time (i.e., after exchange of pretrial disclosures, after completion of depositions, after disposition or dispositive motions, etc.)

The parties do not believe that the case is appropriate for voluntary arbitration or mediation at this time. Mediation may be appropriate at a future stage of the case.

15. Is this case appropriate for bifurcation?

No.

16. An interim status/settlement conference (with clients in attendance), should be held:

At a date and time set by the Court.

17. Do the parties consent to the trial being conducted by a Magistrate Judge?

No.

18. Identify any other issues to address at the Rule 16 Scheduling Conference.

None at this time.